

EC-DECLARATION OF CONFORMITY
CLASSIQSwabs™ in tube - Sarstedt
MEDICAL DEVICE

Manufacturer: Copan Italia S.p.A.
Via Perotti, 10
25125 Brescia, Italia

European Representative: N.A.

Product family: Dry Fiber Swabs - CLASSIQSwabs™ in tube
(See the attached product list "CLASSIQSwabs™ in tube - Sarstedt")

Classification
(according to 93/42/EEC): Class IIa, Rule 6

Conformity assessment
route: Annex II, excluding Section 4 (MDD)

Under our own sole responsibility, we herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices and following amendments. All supporting documentation is retained under the premises of the manufacturer.

This declaration is supported by the Quality System certification based on the standard **EN ISO 13485:2016**
Quality Management System certificate

Notified Body: TÜV SUD PRODUCT SERVICE GmbH,
Ridlerstraße 65, 80339 München-Germany,
Notified Body Identification Number 0123

EC Certificate(s): G1 073936 0014 Rev. 03

Valid until: 26th May 2024

PRODUCT LIST

ClassiqSwabs™ in tube - Sarstedt

CODE	DESCRIPTION
80.1301	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
80.1303	PLAIN SWAB STERILE ALUMINIUM APPLICATOR RAYON TIPPED

Place, Date of Issue: Brescia, 20th March 2020



Elisabetta Zanella
Chief Regulatory Officer